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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,610,163

MAILED

JAN 23 2007

CENTRAL REEXAMINATION UNIT

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,610,163, which claims the active ingredient in the human drug product, Spiriva® HandiHaler® (tiotropium bromide inhalation powder) and methods of use of the active ingredient in Spiriva® HandiHaler® (tiotropium bromide inhalation powder), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,421 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,421 days.

It is noted that a reissue application has been filed for U.S. Patent No. 5,610,163. The reissue application has been assigned U.S. application serial no. 11/254,213. Currently, the reissue application is pending and has not yet reached final disposition. The claims as amended currently read on the approved human drug product, Spiriva® HandiHaler® (tiotropium bromide inhalation powder). Should applicant for patent term extension require that the certificate of extension issue in the reissue grant, then applicant for patent term extension should request a stay of these proceedings in order for the reissue application to be granted and issue.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of January 27, 2006, (71 Fed. Reg. 4592), would be 1,639 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (2,557 - 801) + 761
	=	1,639 days (4.5 years)

Since the regulatory review period began January 1, 1995, before the patent issued (March 11, 1997), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From January 1, 1995, to and including, March 11, 1997, is 801 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,639 days, would extend the patent from March 11; 2014, to September 5, 2018, which is beyond the 14-

year limit (the approval date is January 20, 2004, thus the 14 year limit is January 20, 2018). The period of extension is thus limited to 1,421 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, March 11, 2014, to and including, January 30, 2018, or 1,421 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,610,163
Granted:	March 11, 1997
Original Expiration Date[1]:	March 11, 2014
Applicant:	Rolf Banholzer et al.
Owner of Record:	Boehringer Ingelheim Pharma GMBH & Co. KG
Title:	New Esters of Thienyl Carboxylic Acids and Amino Alcohols and their Quaternization Products
Product Trade Name:	Spiriva® HandiHaler® (tiotropium bromide inhalation powder)
Term Extended:	1,421 days
Expiration Date of Extension:	January 30, 2018

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: Spiriva® HandiHaler®
(tiotropium bromide
inhalation powder)

FDA Docket No.: 2004E-0304